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09/529,575	04/14/2000	FRANCIS JAMES ROURKE	7042-R	9622

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THE PROCTER & GAMBLE COMPANY  
INTELLECTUAL PROPERTY DIVISION - WEST BLDG.  
WINTON HILL BUSINESS CENTER - BOX 412  
6250 CENTER HILL AVENUE  
CINCINNATI, OH 45224

EXAMINER
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ANDERSON, CATHARINE L

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 June 2007 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 31-32, 36, 42-44, 46-48, and 52-53 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 32, 36, 42-44, 46, 48, and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roe (5,607,760) in view of Cadwell (5,874,164).

With respect to claims 31, 32, 36, 42 and 44, Roe discloses all aspects of the claimed invention with the exception of the protease inhibitor being pentamidine and present in the amount of 0.0001-30% by weight. Roe discloses a disposable wearable article comprising a liquid permeable topsheet 520, a liquid impervious backsheets 530,

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and an absorbent core 540. The topsheet comprises a delivery system in the form of a lotion, as disclosed in column 3, lines 3-5. The lotion includes an antibacterial, as disclosed in column 23, lines 24-31.

Cadwell teaches the application of an antibacterial protease inhibitor, pentamidine, to the topsheet of an absorbent article, as described in column 55, lines 16-19 and 28. It would have been obvious to one of ordinary skill in the art at the time of invention to provide the lotion of Roe with pentamidine, as taught by Cadwell, to yield the predictable result of providing the lotion with antimicrobial activity.

The lotion of Roe is applied to the topsheet in an amount that will impart the desired therapeutic benefits of the lotion without saturating the topsheet, as disclosed in column 24, lines 1-12. It would therefore have been obvious to one of ordinary skill in the art at the time of invention to apply the lotion in an amount such that the protease inhibitor would be present in the article in a range of about 0.0001% to about 30% by weight because there would have been a reasonable expectation of success that such an amount would provide a therapeutic benefit without requiring so much lotion that the topsheet would be saturated.

The  $IC_{50}$  is defined in the instant specification on page 7 as being dependant on the concentration of protease inhibitor and the rate of substrate cleavage of the protease inhibitor. The rate of substrate cleavage is dependent on the individual protease inhibitor, and pentamidine is disclosed in the specification as being a suitable protease inhibitor. Therefore, pentamidine, when present in the claimed concentration,

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inherently has an  $IC_{50}$  of about 500  $\mu\text{M}$  or less, no more than 100  $\mu\text{M}$ , and as a result is capable of producing at least a 10% reduction in substrate hydrolysis by a protease.

With respect to claim 43, the lotion is transferable to the skin of a wearer, as disclosed in column 25, lines 25-27.

With respect to claim 46, the deliver system contains the protease inhibitor as molecules, or particles, as disclosed by Cadwell in column 55, line 37.

With respect to claim 48, the lotion is applied to the wearer-contacting surface of the topsheet, as disclosed in column 25, lines 25-27.

With respect to claims 52 and 53, the lotion is applied in a plurality of stripes with a region of the topsheet not containing lotion, as shown in figure 2.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,355,858 discloses the use of protease inhibitors in absorbent materials.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Lynne Anderson whose telephone number is (571) 272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*WA*

cla

September 20, 2007

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

